payment amounts for the list of codes made available to the public.

(c) Not fewer than 30 days after publication of the notice in the FEDERAL REGISTER, CMS convenes a meeting that includes representatives of CMS officials involved in determining payment amounts, to receive public comments and recommendations (and data on which the recommendations are based).

(d) Considering the comments and recommendations (and accompanying data) received at the public meeting, CMS develops and makes available to the public (through an Internet Web site and other appropriate mechanisms) a list of—

(1) Proposed determinations with respect to the appropriate basis for establishing a payment amount for each code, with an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments within a specified time period on the proposed determination; and

(2) Final determinations of the payment amounts for tests, with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions from the public.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007]

§ 414.508 Payment for a new clinical diagnostic laboratory test.

For a new clinical diagnostic laboratory test that is assigned a new or substantially revised code on or after January 1, 2005, CMS determines the payment amount based on either of the following:

(a) *Crosswalking*. Crosswalking is used if it is determined that a new test is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(1) CMS assigns to the new test code, the local fee schedule amounts and national limitation amount of the existing test.

(2) Payment for the new test code is made at the lesser of the local fee schedule amount or the national limitation amount.

(b) *Gapfilling*. Gapfilling is used when no comparable existing test is available.

(1) In the first year, carrier-specific amounts are established for the new test code using the following sources of information to determine gapfill amounts, if available:

(i) Charges for the test and routine discounts to charges;

(ii) Resources required to perform the test;

(iii) Payment amounts determined by other payers; and

(iv) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

(2) In the second year, the test code is paid at the national limitation amount, which is the median of the carrier-specific amounts.

(3) For a new test for which a new or substantially revised HCPCS code was assigned on or before December 31, 2007, after the first year of gapfilling, CMS determines whether the carrier-specific amounts will pay for the test appropriately. If CMS determines that the carrier-specific amounts will not pay for the test appropriately, CMS may crosswalk the test.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007]

§ 414.509 Reconsideration of basis for and amount of payment for a new clinical diagnostic laboratory test.

For a new test for which a new or substantially revised HCPCS code was assigned on or after January 1, 2008, the following reconsideration procedures apply:

(a) *Reconsideration of basis for payment*. (1) CMS will receive reconsideration requests in written format for 60 days after making a determination of the basis for payment under §414.506(d)(2) regarding whether CMS should reconsider the basis for payment and why a different basis for payment would be more appropriate. If a requestor recommends that the basis for payment should be changed from gapfilling to crosswalking, the requestor may also recommend the code or codes to which to crosswalk the new test.

(2)(i) A requestor that submitted a request under paragraph (a)(1) of this section may also present its reconsideration request at the public meeting convened under §414.506(c), provided that the requestor requests an opportunity to present at the public meeting as part of its written submission under paragraph (a)(1) of this section.

(ii) If the requestor presents its reconsideration request at the public meeting convened under §414.506(c), members of the public may comment on the reconsideration request verbally at the public meeting and may submit written comments after the public meeting (within the timeframe for public comments established by CMS).

(3) Considering reconsideration requests and other comments received, CMS may reconsider its determination of the basis for payment. As the result of such a reconsideration, CMS may change the basis for payment from crosswalking to gapfilling or from gapfilling to crosswalking.

(4) If the basis for payment is revised as the result of a reconsideration, the new basis for payment is final and is not subject to further reconsideration.

(b) *Reconsideration of amount of payment*—(1) *Crosswalking.* (i) For 60 days after making a determination under §414.506(d)(2) of the code or codes to which a new test will be crosswalked, CMS receives reconsideration requests in written format regarding whether CMS should reconsider its determination and the recommended code or codes to which to crosswalk the new test.

(ii)(A) A requestor that submitted a request under paragraph (b)(1)(i) of this section may also present its reconsideration request at the public meeting convened under §414.506(c), provided that the requestor requests an opportunity to present at the public meeting as part of its written submission under paragraph (b)(1)(i) of this section.

(B) If a requestor presents its reconsideration request at the public meeting convened under §414.506(c), members of the public may comment on the reconsideration request verbally at the public meeting and may submit written comments after the public meeting (within the timeframe for public comments established by CMS).

(iii) Considering comments received, CMS may reconsider its determination of the amount of payment. As the result of such a reconsideration, CMS may change the code or codes to which the new test is crosswalked.

(iv) If CMS changes the basis for payment from gapfilling to crosswalking as a result of a reconsideration, the crosswalked amount of payment is not subject to reconsideration.

(2) *Gapfilling.* (i) By April 30 of the year after CMS makes a determination under §414.506(d)(2) or §414.509(a)(3) that the basis for payment for a new test will be gapfilling, CMS posts interim carrier-specific amounts on the CMS Web site.

(ii) For 60 days after CMS posts interim carrier-specific amounts on the CMS Web site, CMS will receive public comments in written format regarding the interim carrier-specific amounts.

(iii) After considering the public comments, CMS will post final carrier-specific amounts on the CMS Web site.

(iv) For 30 days after CMS posts final carrier-specific amounts on the CMS Web site, CMS will receive reconsideration requests in written format regarding whether CMS should reconsider the final payment amounts and the appropriate national limitation amount for the new test.

(v) Considering reconsideration requests received, CMS may reconsider its determination of the amount of payment. As the result of a reconsideration, CMS may revise the national limitation amount for the new test.

(3) For both gapfilled and crosswalked new tests, if CMS revises the amount of payment as the result of a reconsideration, the new amount of payment is final and is not subject to further reconsideration.

(c) *Effective date.* If CMS changes a determination as the result of a reconsideration, the new determination regarding the basis for or amount of payment is effective January 1 of the year following reconsideration. Claims for services with dates of service prior to the effective date will not be reopened or otherwise reprocessed.

(d) *Jurisdiction for reconsideration decisions.* Jurisdiction for reconsidering a determination rests exclusively with the Secretary. A decision whether to

reconsider a determination is committed to the discretion of the Secretary. A decision not to reconsider an initial determination is not subject to administrative or judicial review.

[72 FR 66401, Nov. 27, 2007, as amended at 73 FR 2432, Jan. 15, 2008]

§ 414.510 Laboratory date of service for clinical laboratory and pathology specimens.

The date of service for either a clinical laboratory test or the technical component of physician pathology service is as follows:

(a) Except as provided under paragraph (b) of this section, the date of service of the test must be the date the specimen was collected.

(b)(1) If a specimen was collected over a period that spans 2 calendar days, then the date of service must be the date the collection ended.

(2) In the case of a test performed on a stored specimen, if a specimen was stored for—

(i) Less than or equal to 30 calendar days from the date it was collected, the date of service of the test must be the date the test was performed only if—

(A) The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;

(B) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(C) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(D) The results of the test do not guide treatment provided during the hospital stay; and

(E) The test was reasonable and medically necessary for the treatment of an illness.

(ii) More than 30 calendar days before testing, the specimen is considered to have been archived and the date of service of the test must be the date the specimen was obtained from storage.

(3) In the case of a chemotherapy sensitivity test performed on live tissue, the date of service of the test must be the date the test was performed only if—

(i) The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;

(ii) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(iii) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(iv) The results of the test do not guide treatment provided during the hospital stay; and,

(v) The test was reasonable and medically necessary for the treatment of an illness.

(4) For purposes of this section, ''chemotherapy sensitivity test'' means a test identified by the Secretary as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. The Secretary identifies such tests through program instructions.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66402, Nov. 27, 2007]

Subpart H—Fee Schedule for Ambulance Services

SOURCE: 67 FR 9132, Feb. 27, 2002, unless otherwise noted.

§ 414.601 Purpose.

This subpart implements section 1834(l) of the Act by establishing a fee schedule for the payment of ambulance services. Section 1834(l) of the Act requires that, except for services furnished by certain critical access hospitals (see § 413.70(b)(5) of this chapter), payment for all ambulance services, otherwise previously payable on a reasonable charge basis or retrospective reasonable cost basis, be made under a fee schedule.

§ 414.605 Definitions.

As used in this subpart, the following definitions apply to both land and water (hereafter collectively referred to as ''ground'') ambulance services and to air ambulance services unless otherwise specified:

Advanced life support (ALS) assessment is an assessment performed by an ALS crew as part of an emergency response